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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/898,736	07/23/1997	THEO COPPENS	61944	6351

7590 12/26/2001

FITCH EVEN TABIN AND FLANNERY  
SUITE 900  
135 SOUTH LASALLE STREET  
CHICAGO, IL 606034277

EXAMINER

SHERRER, CURTIS EDWARD

ART UNIT

PAPER NUMBER

1761

DATE MAILED: 12/26/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

HJZ

<b>Office Action Summary</b>	Application No. <b>08/898,736</b>	Applicant(s) <b>Coppens et al.</b>
	Examiner <b>Curtis E. Sherrer</b>	Art Unit <b>1761</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1)  Responsive to communication(s) filed on Oct 14, 2001

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

#### Disposition of Claims

4)  Claim(s) 1, 3-9, 13-24, 27-31, 33, and 43-83 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1, 3-9, 13-24, 27-31, 33, and 43-83 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

15)  Notice of References Cited (PTO-892)

18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16)  Notice of Draftsperson's Patent Drawing Review (PTO-848)

19)  Notice of Informal Patent Application (PTO-152)

17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20)  Other: \_\_\_\_\_

**Part III DETAILED ACTION**

***Drawings***

1. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

***Specification***

2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 65-81 been renumbered 67-83.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 72-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have amended claims to recite the phrase "an amount of at least  $1 \times 10^2$  per gram" and while the specification provides basis for this phrase it exist as a lower limit to a range. As the claim now reads, there is no upper limit to this range.

5. Claims 1, 3-9, 13-24, 27-31, 33, and 43-83 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

6. Applicants have now supplied numerous documents (see Declaration Re Availability of Microorganism at ATCC) in order to demonstrate that all of the claimed organisms are enabled. Applicants are first reminded that enablement must be demonstrated as occurring prior to the application date. It is unclear when the organisms listed in said Declaration were deposited. Further, as previously stated, the organisms listed in the Markush group encompass approximately 10,000 organisms and this amount of organisms is not represented in said Declaration.

7. Second, Applicants state that "the Examiner agreed that if an organism is on deposit, it can be germinated." (Emphasis by applicants). The examiner, in his quest to educate himself on the technology of germinating spores, relied on representations from applicants, in the last interview, to come to this conclusion. The examiner admits that he is not an expert in the field

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of spore technology. Therefore, any admission by the examiner is based on information provided by applicants or discovered by the examiner in his search. The examiner notes that knowing that one "can" activate a spore does not equate to "knowing how to" activate a spore.

8. It is noted, that applicants have now supplied the examiner with the needed articles that disclose spore technology and the examiner wishes to express his thanks. After a review of the numerous disclosures, the examiner has arrived at certain conclusions and inquiries.

9. It is first noted for the record that applicants disclose, in their specification, that activated spores have one of the following properties: the size of the spore is increased by a factor preferably between 1.2 and 10 over their dormant size and/or one or more germ tubes per spore are formed. (Page 12 of specification). Applicants also disclose that activated spores are prepared by subjecting them to environmental changes, such as preferably one or more of the following: cycles of wetting and/or drying; addition of appropriate nutritional supplies or spore elements; exposure to temperature changes; and/or exposure to changes in pH. Applicants also state that the activated spores may be introduced during the various malting or steeping stages before or after immersion of the cereal.

10. As to the conclusions, spore properties, as to how they will be activated, is based on how the spores are prepared. Activation characteristics are based (among other things) on the "after-ripening" storage time that is required to obtain activation; what temperatures the spore has previously been exposed to and for what duration, the pH of existing spores, and whether any

nutrients present with the spores. These parameters will determine the length of time to activate the spores, and how the spores look when they are activated, e.g., the amount of swelling.

11. Applicants discuss only one specific species of organism in their specification. *Rhizopus oryzae* ATCC 9363 is prepared by applicants by growing the strain on PDA for approximately 10 days at 28 C, harvesting the spores with a sterile saline solution and centrifugation. The spores are activated by being placed in an acidified TSB, pH of 4.0 and a temperature of 42 C for 5 to 6 hours. Applicants disclose no other specific organisms or specific methods of activating organisms.

12. With respect to the Coppens Declaration, it is noted that Coppens prepares the spores of the prior art by growing organisms for seven days at 28 C, taking the sporulating culture and incubating them for 3 weeks at 20C. It appears that the prior art actually takes fungi cells (and does not mention using "sporulating" organisms) and incubates them for 3 weeks at 20 C to get obtain spores.

13. Coppens states that the entire culture was homogenized and then one would expect the photographs to show more than just spores, such as non-dormant organisms. Coppens states that no photos were provided of spores occurring in flocs or pairs and that were not attached to mycelium fragments. It is also noted that the scale used to measure the size of the spores, where it appears that one division represent 10 microns, is too large to accurately determine the size of the spores that measure between 4-7.8 microns.

14. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 1, 2-9, 13-24, 27-31, 33, and 43-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

16. Applicants rely on the term "about" to limit the range of spores being added and the scope of this term and its effect on said range is unknown. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

17. The phase "activated spores" is deemed to be indefinite because its scope is unknown. Specifically, an activation step occurs when dormant spores are transformed into germinated spores, i.e., a short transition period. In Sussman, page 758, Table VI, discloses that activation occurred over 150 minutes for *Neurospora tetrasperma* and then the culture was deemed to be germinating. It is unclear if applicants are claiming the use of organisms that exist in this brief transition phase or merely mean that the organism was at some time activated.

18. Applicants have amended their specification to include the phrase directed to 'an increased activity of an enzyme compared to the activity of an enzyme obtained by moistening and mixing the cereal with dormant spores.' It is not clear at what point the increased enzyme

activity is being measured, e.g., just after the fungi is added, at the end of the barley malting process, etc.

***Claim Rejections - 35 USC § 102/103***

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 1, 3-9, 13-24, 27-31, 33, 43-83 are rejected under 35 U.S.C. 102(b) as being anticipated by or in the alternative rejected under 35 U.S.C. 103(a) as being unpatentable over Gyllang et al (European Brewing Convention (16th Congress)) for the reasons set forth in the last Office Action. In light of the outstanding issues discussed above, a conclusion as to whether the prior art anticipates and/or suggests the claimed invention stands.

21. It is noted, with respect to the issue of obviousness, if it positively shown that Gyllang does not show the use of activated spores, that one of ordinary skill in the art would nevertheless be motivated to use activated spores because dormant spores are metabolically inactive and therefore, to obtain the benefit of using the spores of, they should be activated so that spores can have "a high degree of activity that can affect the composition of the barley kernel." (Page 252). Figure 6 shows the compositional changes that result when using added fungi. Gyllang et al.

state that "the growth of fungi takes place particularly during the germination of the barley under conditions which are optimal for final growth with respect to temperature, moisture and the availability of the nutrients from the barley." Clearly, Gyllang et al. desire the use of germinated growing fungi and to activate the fungi before adding it to the barley would provide the desired compositional changes.

***Response to Arguments***

22. Applicant's arguments filed 10/14/01 have been fully considered but they are not persuasive. See comments above.

23. It is also noted that the showing in the Supplemental Declaration of Coppens (Paper #40) is not commensurate in scope with the broadest claimed invention with respect to the organisms used, the enzymes measured, and step at which the organism is added in the malting process. Further, it is not clear if the data is significantly different.

***Conclusion***

24. No claim is allowed.

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yamada teaches that embryo buds of grain, such as barley, are used to quality seed

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malt with a high number of spores. Koji is typically derived from the organism, *Aspergillus oryzaea*.

26. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Curtis Sherrer whose telephone number is (703) 308-3847. The examiner can normally be reached on Tuesday through Friday from 6:30 to 4:30. The **fax phone number** for this Group is (703)-305-3602.

28. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.



Curtis E. Sherrer  
Primary Examiner  
December 17, 2001